

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN Group Art Unit : 1617
Serial No. : 10/599,519 Examiner : Audrea J. Buckley
Filed : June 22, 2007 Confirmation No. : 1188
Entitled: METHOD FOR DERMATOLOGICAL TREATMENT USING
CHROMOPHORES

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PRE-APPEAL BRIEF REQUEST FOR REVIEW AND ARGUMENTS

Sir:

As set forth in the New Pre-Appeal Brief Conference Pilot Program guidelines dated July 12, 2005, this Pre-Appeal Brief Request for Review sets forth a succinct, concise and focused set of arguments for which the review is being requested. This paper is being filed contemporaneously with a Notice of Appeal and the request form PTO/SB/33. This paper is filed in response to the Final Office Action dated September 2, 2011 (the "Final Office Action") and the Advisory Action dated December 19, 2011.

CLAIM STATUS

Claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32 as presented in the Amendment and Response to Office Action filed June 14, 2011 are currently under consideration in the present application.

ARGUMENTS**I. REJECTIONS UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN**

Claims 1, 3, 4, 6-9 and 27-30 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Publication No. 2003/0159615 by Anderson et al. (the "Anderson Publication") in view of U.S. Patent No. 6,565,532 issued to Yuzhakov et al. (the "Yuzhakov Patent"). Claims 5, 11, 13, 16, 17, 20-23, and 25 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Anderson Publication in view of the Yuzhakov Patent, and further in view of U.S. Patent No. 5,836,998 issued to Mueller et al. (the "Mueller Patent"). Claim 24 stands finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Anderson Publication in view of the Yuzhakov Patent and the Mueller Patent, and further in view of U.S. Publication No. 2002/0091311 of Eppstein et al. (the "Eppstein Publication"). Applicant respectfully asserts that the Anderson Publication, either taken alone or in a purported combination with the Yuzhakov Patent, fails to disclose, teach, or suggest the subject matter recited in independent claims 1 and 11 and the claims which depend from them, for at least the reasons set forth below.

The Anderson Publication relates to permanent tissue markings, such as tattoos, that can be formed by implanting microparticles in the dermis, where such markings may later be removed by

application of energy, such as optical radiation. (See Anderson Publication, Abstract, and paras. [0016], [0133], and [0134]).

The Yuzhakov Patent relates to microneedle arrays that can be used, inter alia, to apply temporary markings to the epidermis of the skin without entering the dermal layer. (See Yuzhakov Patent, Abstract; col. 3, lines 54-59; col. 8, lines 1-14; and col. 41, lines 36-45).

The Eppstein Publication describes methods and apparatus for increasing permeability of a biological membrane using a pyrotechnic charge to form openings therein. (See Eppstein Publication, Abstract, and paragraph [0041]). The methods and apparatus of Eppstein can be used with a substrate containing pigments, where the pigments are forced into the skin by the charge to form a tattoo. (*Id.*, para. [0044]).

The Mueller Patent describes the use of a stencil for body art whereby a stain is applied to a predetermined epidermal area delineated by the stencil. (See Mueller Patent, col. 1, line 65-col. 2, line 11).

A. Independent Claim 1 and Dependent Claims 3-9, 22-23, 25 and 27-31

Independent claim 1 relates to a **method for fractional wounding of skin** that comprises:

applying at least one chromophore in a specific pattern to a predetermined area of the skin, wherein the specific pattern corresponds to a desired pattern of fractional wounding of the skin; and

applying electromagnetic radiation to the predetermined area of the skin **so as to produce a plurality of thermally-damaged regions in at least an epidermal portion of the skin based on an interaction between the at least one chromophore and the electromagnetic radiation.**

Thus, independent claim 1 recites a **method for fractional wounding of skin that is based on an interaction between at least one chromophore and an electromagnetic radiation applied to an area in at least an epidermal portion of the skin.** It is respectfully asserted that at least such recited subject matter of independent claim 1 is in no way taught, suggested or disclosed in the Anderson Publication, taken alone or in the purported combinations of references relied on by the Examiner.

As an initial matter, Applicant respectfully asserts that the Anderson Publication teaches away from **generating thermally-damaged regions in the skin** as recited in independent claim 1. For example, the Anderson Publication describes the use of fluencies that are “well tolerated by the skin” and that “higher laser fluencies **that do not injure the tissue** can be used...” (See Anderson Publication, para. [0150]; **emphasis added**). The Anderson Publication further states that “[t]he preferred electromagnetic radiation pulse duration used to effect mechanical rupture or thermal alteration of a microparticle is approximately less than or equal to the thermal relaxation time ... of the microparticle. ... This pulse duration results in thermal confinement at the microparticle, **reducing secondary damage to surrounding tissue.**” (*Id.*, para. [0151]; **emphasis added**). The Anderson Publication also notes that “Ideally, short, powerful light pulses are absorbed specifically by tattoo pigment particles **with little or no absorption by surrounding tissue**, thereby causing the particles of pigment to break apart **with minimal damage to neighboring skin structures.**” (*Id.*, para. [0012]; **emphasis added**). In describing a further embodiment using microparticles that are not ruptured, the

Anderson Publication states: “Cells are unlikely to be damaged during tissue marking removal or even to be ‘aware’ of treatment.” (*Id.*, para. [0154]; **emphasis added**).

The subject matter of independent claim 1 recites a method for **fractional wounding of skin** (e.g., in at least an epidermal portion thereof) by generating thermal damage, whereas the Anderson Publication consistently teaches that **damaging the skin tissue should be minimized or avoided**. Accordingly, the Anderson Publication teaches away from generating **any** thermal damage in the skin tissue, and therefore it does not teach or suggest the formation of any **desired pattern of fractional wounding of the skin**, as explicitly recited in independent claim 1. To the extent that any thermal damage of skin tissue is mentioned in the Anderson Publication, it is **only** mentioned in the context of *reducing or avoiding* any such secondary damage to skin tissue.

Thus, Applicant respectfully asserts that the Anderson Publication teaches away from the claimed invention as recited in independent claim 1, which is a ‘significant’ factor in determining nonobviousness. (See MPEP §§ 2141.02 and 2145(X)(D); see also *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997) [stating that a *prima facie* case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention]).

The Anderson Publication also teaches away from the subject matter of independent claim 1 because the Anderson Publication describes only a method for removing microparticles containing chromophores that are located in the **dermis** region of skin tissue, rather than providing chromophores in skin tissue that will generate thermal damage in the **epidermis** upon irradiation as recited in claim 1. (See Anderson Publication, paras. [0005], [0012], [0133], and [0134]). For example, the Anderson Publication states, in part, the following:

“Tissue markings in skin **must** be properly placed to provide permanent markings. Skin is composed of the outermost epidermis, generated by the constantly dividing stratum basale, and the underlying dermis. Dermal cells, such as fibroblasts, mast cells, and others, which do not generally replicate, are located within a resilient proteinaceous matrix. **It is the upper dermis, below the stratum basale, into which the microparticles are implanted to provide a tissue marking (such as a tattoo).**” (*Id.*, para. [0133]; **emphasis added**).

The Examiner attempts to overcome this further deficiency in the Anderson Publication through a purported combination with the Yuzhakov Patent. (See Final Office Action, pages 4-5). The Yuzhakov Patent describes the use of microneedle arrays to introduce particles or pigments into skin tissue. The Examiner alleges that the Anderson and Yuzhakov references are “directed to tattoos created by damaging and implanting active agents into layers of skin.” (See *id.*, page 5). However, such ‘damaging’ is not the thermal damage generated by exposing chromophores to radiation, as recited in independent claim 1.

The Examiner further alleges that “it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to select the epidermal layer as the chromophore deposition site if semi-permanence or less pain was desired, based on the teaching of Yuzhakov.” Applicant asserts that it would not be obvious to combine this particular aspect of the Yuzhakov disclosure (**epidermal deposition**), relied on by the Examiner, with the teachings of the Anderson Patent, which specifies that the microparticles **must** be placed in the **dermis** (as noted above).

The Yuzhakov Patent states, in part, that “[t]he preferred inks contain particles of a certain minimum size that will not diffuse too far through the skin, thereby maintaining a high resolution, and **if placed into the epidermis, the marking will disappear from the skin after a time period.**” (See

Yuzhakov Patent, col. 8, lines 10-14; **emphasis added**). Applicant respectfully asserts that one of ordinary skill in the art would not look to deposit the permanent-marking **dermal** microparticles of the Anderson Publication using the **epidermal** deposition needle arrays described in the Yuzhakov Patent, because epidermally-deposited inks will disappear spontaneously (as the epidermis sloughs off), as taught by the Yuzhakov Patent.

Clearly, the Yuzhakov Patent fails to teach or suggest any method or apparatus that generates thermal damage in skin tissue. The Anderson Publication *teaches away* from generating thermal damage in the skin (dermis) when irradiating microparticles deposited in the dermis to remove skin markings. The purported combination of the Anderson Publication with the Yuzhakov Patent relied on by the Examiner (which should not be made in the first place) also fails to teach or suggest any generation of a desired pattern of thermal damage in the epidermis, as recited in independent claim 1. One of ordinary skill in the art would certainly not look to either the Anderson Publication or the Yuzhakov Patent to purposely generate regions of thermal damage in a desired pattern of fractional wounding, much less combine them to do so. Accordingly, Applicant respectfully asserts that one having ordinary skill in the art would be taught away from producing or generating **thermally damaged regions in an epidermal portion of tissue** based on the explicit disclosure of the Anderson Patent and the understanding in the art.

Therefore, for at least such reasons, the 35 U.S.C. § 103(a) rejections of claims 1, 3-9, 22-23, 25 and 27-31 should be withdrawn.

B. Independent Claim 11 and Dependent Claims 13, 16, 17, 20, 21, and 32

Independent claim 11 relates to a method for fractional wounding of skin that includes:

applying at least one chromophore to a predetermined area of the skin;

applying a mask with a specific pattern over the predetermined area of the skin, wherein the specific pattern corresponds to a desired pattern of fractional wounding of the skin; and

applying electromagnetic radiation to the predetermined area so as to generate regions of a thermal injury in at least an epidermal portion of the skin based on an interaction between the electromagnetic radiation and the at least one chromophore, wherein the regions are formed in a predetermined pattern.

As indicated above with respect to independent claim 1, the Anderson Patent *teaches away* from generating thermal damage in skin when irradiating microparticles provided in the dermis, and the Yuzhakov Patent, even if combinable with the Anderson Publication (and Applicant does not agree that it is), fails to cure this deficiency. The Examiner relies on the Mueller Patent, which describes use of an adhesive stencil to allow a decorative stain to be applied to an epidermis in a particular pattern, in combination with the Anderson and Yuzhakov references in rejecting independent claim 11 and several claims that depend therefrom.

As an initial matter, it is respectfully asserted that the Mueller Patent fails to cure the deficiencies in the purported combination of the Anderson Publication and Yuzhakov Patent to render obvious any **generation of regions of thermal injury in the epidermis based on an interaction between electromagnetic radiation and the at least one chromophore**, as recited in independent claim 11.

Further, the stencil described in the Mueller Patent is used to apply the chromophore to the skin in a particular pattern. In contrast, the method recited in independent claim 11 includes applying a chromophore to the skin **without mentioning a mask, then applying a mask** with a specific pattern, and **then applying radiation** that interacts with the chromophores to generate regions of thermal damage. Independent claim 11 recites the use of the mask **after** a chromophore is applied to the skin, and therefore the mask/stencil does **not** need to be used to form a particular pattern of a chromophore as described in the Mueller Patent.

Therefore, the 35 U.S.C. § 103(a) rejections of claims 11, 13, 16, 17, 20, 21, and 32 should be withdrawn.

C. Dependent Claim 24

Claim 24 stands rejected under 35 U.S.C. §103(a) based on the purported combination of the Anderson, Yuzbakov, and Mueller references, and further in view of the Eppstein Publication. The Examiner relies on the Eppstein Publication solely for the feature of a paraffin as recited in claim 24. Applicant asserts that claim 24, which depends indirectly from claim 1, is also not rendered obvious for at least the reasons provided above with respect to independent claim 1.

Therefore, the 35 U.S.C. § 103(a) rejection of claim 24 should be withdrawn.

II. CONCLUSION

In light of the foregoing, Applicants respectfully assert that all pending claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32 are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner and/or the panel are invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

This Pre-Appeal Brief Request for Review is submitted contemporaneously with a Notice of Appeal. Accordingly, please charge Deposit Account No. 50-2054 in the amount of \$270.00 (small entity) for Notice of Appeal fee, and a one-month extension of time fee under 37 C.F.R. § 1.136(a). No further fees or petitions are believed to be required. If any such petitions or fees are necessary, please consider this a request therefore and authorization to charge Deposit Account No. 50-2054.

Respectfully submitted,

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